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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,663	06/21/2006	Joachim Fensterle	281782US0PCT	7224
22850	7590	08/22/2008	EXAMINER	
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			SWARTZ, RODNEY P	
			ART UNIT	PAPER NUMBER
			1645	
			NOTIFICATION DATE	DELIVERY MODE
			08/22/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/559,663	Applicant(s) FENSTERLE ET AL.	
	Examiner Rodney P. Swartz, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-12,14,15 and 17-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-12,14,15 and 17-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' Response to Office Action, received 11 April 2008, is acknowledged. Claims 1, 2, 3, 4, 6, 7, 8, 9, 11, 12, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, and 28 have been amended. Claims 5 and 13 have been canceled.
2. Claims 1-4, 6-12, 14, 15, and 17-28 are pending and under consideration.

Rejection/Objections Moot or Withdrawn

3. The rejection of claim 13 under 35 U.S.C. 112, first paragraph, scope of enablement for methods of treatment of disorders, is moot in light of the cancelation of the claim.
4. The rejection of claims 5 and 13 under 35 U.S.C. 112, second paragraph, as being indefinite for identity of reference subject for autologous, allogeneic or xenogeneic, is moot in light of the cancelation of the claims.
5. The rejection of claims 5 and 13 under 35 U.S.C. 112, second paragraph, as being indefinite for "active substance" is moot in light of the cancelation of the claims.
6. The rejection of claim 13 under 35 U.S.C. 112, second paragraph, as being indefinite for "disorders", is moot in light of the cancelation of the claim.
7. The objection to Figure 2 is withdrawn in light of the replacement figure.
8. The objection to Figure 3 is withdrawn in light of the replacement figure.
9. The objection to Figure 4 is withdrawn.
10. The objection to claim 1 is withdrawn in light of the amendment of the claim.
11. The objection to claim 4 is withdrawn in light of the amendment of the claim.
12. The objection to claim 8 is withdrawn in light of the amendment of the claim.
13. The objection to claim 12 is withdrawn in light of the amendment of the claim.
14. The objection to claim 22 is withdrawn in light of the amendment of the claim.

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15. The rejection of claims 1, 3, 4, 7, 8, and 19-28 under 35 U.S.C. 101, non-statutory subject matter, is withdrawn in light of the amendment of the claims.

16. The rejection of claims 1-4, 6-12, 14, 15, and 17-28 under 35 U.S.C. 112, second paragraph, as being indefinite for identity of reference subject for autologous, allogeneic or xenogeneic, is withdrawn in light of the amendment of the claims.

17. The rejection of claims 6-12, 14, 15, and 17-28 under 35 U.S.C. 112, second paragraph, as being indefinite for "active substance" is withdrawn in light of the amendment of the claim.

18. The rejection of claim 7 under 35 U.S.C. 112, second paragraph, as being indefinite for "associated" is withdrawn in light of the amendment of the claim.

19. The rejection of claim 8 under 35 U.S.C. 112, second paragraph, insufficient antecedent basis for the limitation "claim 1, wherein the active substance" in line 2, is withdrawn in light of the amendment of the claim.

20. The rejection of claims 9-12, 14, 15, and 17-18 under 35 U.S.C. 112, second paragraph, as being indefinite for "disorders", is withdrawn in light of the amendment of the claims.

21. The rejection of claim 9 under 35 U.S.C. 112, second paragraph, insufficient antecedent basis for the limitation "claim 1... wherein the active substance and/or vaccine antigen", is withdrawn in light of the amendment of the claim.

Rejections Maintained

22. The rejection of claim 12 under 35 U.S.C. 112, second paragraph, as being indefinite for identity of cells, is maintained.

Applicants argue that the amendment of the claim obviates the indefiniteness.

The examiner has considered applicants' argument, but does not find it persuasive in as far as the identity of the dendritic cells. While the identity of macrophages are now "the

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macrophages" of claim 9, the identity of claimed dendritic cells remains simply as "dendritic" cells.

23. The rejection of claims 17-18 under 35 U.S.C. 112, second paragraph, as being indefinite for "foreign", is maintained.

Applicants argue that the amendment of the claims obviates the rejection.

The examiner has considered applicants' argument, but does not find it persuasive. As newly amended, the claims are now directed to a recombinant DNA comprising a "heterologous nucleotide sequence". As in the original rejection explanation, it is unclear to what the nucleotide sequence is "heterologous", i.e., the host subject, the mammalian cell, or the bacterium.

24. The rejection of claims 9-12, 14, 15, and 17-18 under 35 U.S.C. 112, first paragraph, scope of enablement for methods of treatment of disorders, is maintained.

Applicants argue that the claims, newly amended to recite a method for prophylaxis or therapy of "neoplastic diseases, immune diseases, autoimmune diseases, chronic inflammations, and organ transplants, are enabled based upon the teachings in the specification and the Declaration of Joachim Fensterle, one of the applicants on the instant application.

The examiner has considered applicants' argument, in light of the amendment of the claims and the Declaration of Dr. Fensterle, but does not find it persuasive. As stated in the original rejection explanation, the only working examples are macrophages and tumor cells infected with *S. typhimurium* or *L. monocytogenes* injected into mice with no actual examples of the claimed methods for prophylaxis or therapy of any/all disorders. The Declaration of Dr. Fensterle recites an experiment wherein *L. monocytogenes* delta *aroA* was injected in mice. The mice had previously been transplanted with breast cancer cells, and tumors allowed to

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grow up to a tumor diameter of approximately 0.5 cm before injection of the *L. monocytogenes* delta aroA. The data collected included: 1) number of CFU of *L. monocytogenes* delta aroA present in the tumor tissue, and 2) ability of tumor lysates to form relative amounts of MeP from the substrate MePdR. However, the Declaration data do not show actual tumor regression following treatment with the *L. monocytogenes* delta aroA. In addition, neither the instant specification nor the Declaration show prophylaxis or therapy of "neoplastic diseases, immune diseases, autoimmune diseases, chronic inflammations and organ transplants" as is currently being claimed. Thus, the claims remain rejected for insufficient enablement for the broad scope of the inventions being claimed.

Claim Rejections - 35 USC § 102

25. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

26. Claims 1-4, 6-8, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Curtiss et al (U.S. Pat. No. 6,383,496).

The claims are drawn to an isolated mammalian cell (macrophage, dendritic cell, granulocyte, lymphocyte, tumor or tissue cell) loaded with a bacteria. The recitation of intended use, i.e., for prophylaxis or therapy of a disorder, carries no patentable weight.

Curtis, III, et al. teach an isolated mammalian cell (murine macrophage J774; rat bone marrow macrophage) loaded with a bacteria (*Salmonella typhimurium*, x3339, and *Salmonella typhimurium*, x4873) (Figure 1; Figure 2). The bacteria can be attenuated and can comprise a

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gene or portion thereof within a eukaryotic expression cassette (col. 5, line 36, to col. 6, line 29; col. 13, line 59 to col. 14, line 19; col. 27, line 7 to col. 30, line 49).

27. Claims 1-4, 6-8, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Curtiss et al (U.S. Pat. No. 6,024,961).

The claims are drawn to an isolated mammalian cell (macrophage, dendritic cell, granulocyte, lymphocyte, tumor or tissue cell) loaded with a bacteria. The recitation of intended use, i.e., for prophylaxis or therapy of a disorder, carries no patentable weight.

Curtis, III, et al. teach an isolated mammalian cell (murine macrophage J774; rat bone marrow macrophage) loaded with a bacteria (*Salmonella typhimurium*, x3339, and *Salmonella typhimurium*, x4873) (Figure 1; Figure 2). The bacteria can be attenuated and can comprise a gene or portion thereof within a eukaryotic expression cassette (col. 3, line 48, to col. 4, line 63; col. 9, line 63 to col. 11, line 6).

Claim Rejections - 35 USC § 112

28. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

29. Claims 20-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are dependent from rejected claims.

Conclusion

30. No claims are allowed.

31. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571)

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272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Shannon Foley, can be reached on (571)272-0898.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

July 16, 2008